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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,801	12/09/2000	David Kenneth Johnson	Johnson 60/17024	2575

7590 09/22/2004

DEANNA J. NELSON
104 TASMAN COURT
CARY, NC 27513

EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/733,801	JOHNSON, DAVID KENNETH	
	Examiner	Art Unit	
	David J Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/30/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

In Office Action dated December 31, 2002, former Examiner Shaver set forth a requirement for restriction. In correspondence dated January 27, 2003, Applicant elected claims 9-21 for examination on the merits. However, upon review of the elected claims, the instant Examiner has discovered additional patentably distinct inventions within claims 9-21, which necessitates further restriction. Consequently, restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to organometallics, classified in class 556, subclass 1, for example.

II. Claim 9, drawn to an immunoassay method, classified in class 436, subclass 528, for example.

III. Claim 10, drawn to an immunoassay method comprising a polyclonal antibody response in an immunized animal, classified in class 436, subclass 74, for example.

IV. Claim 11, drawn to an immunoassay method comprising a monoclonal antibody present in a hybridoma supernatant, classified in class 436, subclass 548, for example.

V. Claims 12-15, drawn to an immunoassay method comprising a metal ion solution, classified in class 73, subclass 61.42, for example.

VI. Claims 16 and 18-19, drawn to an immunoassay method comprising an aqueous extract of a solid sample, classified in class 435, subclass 962, for example.

VII. Claims 17-19, drawn to an immunoassay method comprising a water sample, classified in class 435, subclass 7.1, for example.

VIII. Claims 20-21, drawn to a test kit, classified in class 435, subclass 287.2, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and (II, III, IV, V, VI or VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the product can be used as a contrasting agent.

Inventions I and VIII are related as subcombination and combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a chelating agent and biological binding agent have separate patentable utility as a chelation therapeutic. The subcombination has separate utility such as a contrasting agent.

Inventions II and III are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Invention II requires an aqueous solution thought to contain a biological binding agent, while Invention III requires a polyclonal antibody response in an immunized animal and serum.

Inventions II and IV are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Invention II requires an aqueous solution thought to contain a biological binding agent, while Invention IV requires a monoclonal antibody in a hybridoma supernatant.

Inventions II and V are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Invention II requires a non-target chelate-fluorophore tracer composition, while Invention V requires a metal ion solution.

Inventions II and VI are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Invention II requires a non-target chelate-fluorophore tracer composition, while Invention VI requires an aqueous extract of a solid sample.

Inventions II and VII are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation

because Invention II requires a non-target chelate-fluorophore tracer composition, while Invention VII requires a water sample.

Inventions II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the product can be used as a contrasting agent. This same relationship also applies to inventions III-VIII, IV-VIII, V-VIII, VI-VIII and VII-VIII.

Inventions III and IV are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Invention III requires a polyclonal antibody response in an immunized animal and serum, while Invention IV requires a monoclonal antibody in a hybridoma supernatant.

Inventions III and V are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Invention III requires a polyclonal antibody response in an immunized animal and serum, while Invention V requires a water sample.

Inventions III and VI are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Invention III requires a polyclonal antibody response in an immunized animal and serum, while Invention VI requires an aqueous extract of a solid sample.

Inventions III and VII are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Invention III requires a polyclonal antibody response in an immunized animal and serum, while Invention VII requires a water sample.

Inventions IV and V are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Invention IV requires a monoclonal antibody in a hybridoma supernatant, while Invention V requires a metal ion solution.

Inventions IV and VI are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the different inventions have different modes of operation because Invention IV requires a monoclonal antibody in a hybridoma supernatant, while Invention VI requires an aqueous extract of a solid sample.

Inventions IV and VII are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Invention IV requires a monoclonal antibody in a hybridoma supernatant, while Invention VII requires a water sample.

Inventions V and VI are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Invention V requires a metal ion solution, while Invention VI requires an aqueous extract of a solid sample.

Inventions V and VII are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Invention V requires a composition of claim 1, while Invention VII requires a composition of claim 3.

Inventions VI and VII are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Invention VI requires an aqueous extract of a solid sample, while Invention VII requires a water sample.

Because these inventions are distinct for the reasons given above and the search required for each is not required for the other, restriction for examination purposes as indicated is proper.

A telephone call was made to Agent Deanna Nelson on July 28, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

djv

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09/15/04